



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,320	06/22/2001	Clifton E. Barry III	015280-413100US	7214

20350 7590 04/28/2004

TOWNSEND AND TOWNSEND AND CREW, LLP  
TWO EMBARCADERO CENTER  
EIGHTH FLOOR  
SAN FRANCISCO, CA 94111-3834

EXAMINER

SAKELARIS, SALLY A

ART UNIT	PAPER NUMBER
----------	--------------

1634

DATE MAILED: 04/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# **Advisory Action**

**Application No.**

09/888,320

**Applicant(s)**

BARRY ET AL.

**Examiner**

Sally A Sakelaris

**Art Unit**

1634

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 13 February 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

## **PERIOD FOR REPLY [check either a) or b)]**

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 13 February 2004. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 1-5,8-12,21,22,25,28,29 and 34-48.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

Continuation of 2. NOTE: The proposed amendments will not be entered. Specifically, the amendments extensively modify the claims and as a result will not be entered. The present claim language involving "ethionamide, thiacetazone or thiocarlide" as well as the newly amended mutations to be detected including "a frameshift mutation selected from the group consisting of: a deletion at position 65, an addition at position 567, and an addition at position 811, or a single nucleotide polymorphism which causes an amino acid substitution selected from the group consisting of G43C, P51L, D58A, Y84D, T186K, T342K, and A381P" varies extensively the presently elected and claimed invention. Therefore the recitation of these new compounds and mutations raises new issues that would require further consideration and search.

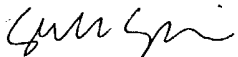
Continuation of 5. does NOT place the application in condition for allowance because: The applicant's amendment requires further search and consideration and does not overcome the presently maintained rejections from the final action sent 8/12/2003. In response to applicant's traversal of the 112 1<sup>st</sup> paragraph rejection addressed in their response in section IIIA., the examiner maintains that the reference to Figure 4C(see final rejection page 8), provides unpredictable results with respect to applicant's arguments that assert 1) any mutation causing an amino acid change in the EtaA gene would confer resistance to the drugs containing a thioamide or a thiocarbonyl and 2) all mutations in EtaA gene are associated with increased resistance to all thioamide and thiocarbonyl containing drugs, since they are well known to reduce the ability of the organism to catalyze S-oxidation. With respect to applicant's cited art, the references are not persuasive as they are not present in Declaration format. In response to applicant's arguments concerning the obviousness rejection over claims 25 and 46, and applicant's assertion that the examiner has "simply picked and chosen from the art to recreate the invention", the examiner maintains that a teaching of Badcock in view of Philipp and in further view of Ahern would have been obvious to one of skill in the art at the time the invention was made. Philipp et al teach the elucidation of genomic organization, the establishment of ordered DNA fragments, and the use of PCR amplification using primers specific to M tuberculosis sequence of genomic DNA in order to facilitate gene mapping data handling and analysis. Considering as applicant pointed out in their response on page 13, that the persons of skill in the art are typically M.D.s and Ph.D.s, that the citation was not deemed to be taken out of context as inherent in these taught procedures are many techniques in molecular biology that can be used for more than one approach, i.e., in order to make the clones based on the shuttle vector, primers specific for the etaA gene could be used. Furthermore, the remaining rejections are also maintained for reasons of record in view of the non-entry of after final amendment.

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Sally Sakelaris whose telephone number is (571)272-0748. The examiner can normally be reached on Monday-Thursday from 7:30AM-5:00PM and Friday from 1:00PM-5:00PM.

If attempts to reach the examiner are unsuccessful, the primary examiner in charge of the prosecution of this case, Jeffrey Fredman, can be reached at (571)272-0742. If attempts to reach the examiners are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (571)272-0782. The official fax number is (703)872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to Chantae Dessau whose telephone number is (571)272-0518.

Sally Sakelaris



4/27/2004



GARY BENZION, PH.D.  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600